DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 25, 2015

Aesculap Implant Systems, LLC
Ms. Lisa Boyle
Regulatory Affairs Manager
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K143443
Trade/Device Name: VEGA Knee System® and Columbus Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Class: Class II
Product Code: JWH
Dated: February 20, 2015
Received: February 23, 2015

Dear Ms. Boyle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K143443

Device Name

VEGA Knee System and Columbus Total Knee System

Indications for Use *(Describe)*

The VEGA Knee System is indicated for use in reconstruction of the diseased knee joint caused by osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, the need to revise failed arthroplasties or osteotomies where pain, deformity or dysfunction persist, and for patients suffering from correctable valgus or varus deformity and moderate flexion contracture.

Posterior Stabilized (PS) components are also for absent or non-functioning posterior cruciate ligament and severe anteroposterior instability of the knee joint.

The VEGA Knee is designed for use with bone cement.

The Columbus Total Knee System is indicated for use in reconstruction of the diseased knee joint caused by osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, the need to revise failed arthroplasties or osteotomies where pain, deformity or dysfunction persist, and for patients suffering from correctable valgus or varus deformity and moderate flexion contracture.

Posterior Stabilized (PS) components are also for absent or non-functioning posterior cruciate ligament and severe anteroposterior instability of the knee joint.

The Columbus Knee is designed for use with bone cement.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

VEGA Knee System and Columbus Total Knee System

February 20, 2015

COMPANY: Aesculap® Implant Systems, LLC
3773 Corporate Parkway
Center Valley, PA 18034

ESTABLISHMENT REGISTRATION NUMBER: 3005673311

CONTACT: Lisa M. Boyle
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lisa.boyle@aesculap.com

DEVICE TRADE NAMES: VEGA Knee System®
Columbus Total Knee System

COMMON NAME: Total Knee System

DEVICE CLASS: CLASS II

PRODUCT CODE: JWH

REGULATION NUMBER: 888.3560

CLASSIFICATION NAME: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi constrained Cemented Prosthesis

SUBSTANTIAL EQUIVALENCE

Aesculap Implant Systems, LLC believes that the introduction of All Poly Tibia posterior stabilizing and cruciate retaining implants with an optional centralizer are substantially equivalent to the currently marketed Aesculap VEGA Knee System® (K101281, K121879, K140452, and K143106), Columbus Total Knee System (K022672; K023788; K053390; K071220; K071449 and K120955) and Triathlon® All-Polyethylene Tibial Implants (K123166).

DEVICE DESCRIPTION

All Poly Tibia posterior stabilizing and cruciate retaining implants are a line extension to the VEGA Knee System® and Columbus Total Knee System, respectively. The posterior stabilizing version is being introduced to the VEGA Knee System® and the cruciate retaining, deep dish version is being introduced to the Columbus Total Knee System. The subject implants are available with an optional centralizer.

VEGA Knee System® is a semi-constrained cemented prosthesis with a posterior stabilized (PS) design. Columbus Total Knee System includes both cruciate retaining and posterior stabilizing variants of the femoral, tibial and meniscal components.

For both knee systems, the femoral component, tibial plateau and extension stems are manufactured from Cobalt Chromium Molybdenum alloy (CoCrMo), available with an optional Zirconium nitride (ZrN) coating. The tibial gliding surface (insert), patella and All Poly Tibia are manufactured from Ultra High Molecular Weight Polyethylene (UHMWPE). The optional centralizer, designed to be used with the All Poly Tibia is made of polymethyl methacrylate (PMMA). The patella and All Poly Tibia incorporate X-ray markers. The materials of the X-ray markers in the patella are wrought stainless steel and the All Poly Tibia X-ray markers consist of a titanium peg and a tantalum ball. The tibial plug is made of PEEK.
VEGA and Columbus Knee Systems are made up of numerous components available in various sizes. The VEGA Knee System® is compatible with Aesculap Columbus cruciate retaining/posterior stabilizing tibial plateaus (CR/PS and CRA/PSA) and augments.
VEGA and Columbus components are sterile and intended for single use only.

INDICATIONS FOR USE

The VEGA Knee System® and the Columbus Total Knee System are indicated for use in reconstruction of the diseased knee joint caused by osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, the need to revise failed arthroplasties or osteotomies where pain, deformity or dysfunction persist, and for patients suffering from correctable valgus or varus deformity and moderate flexion contracture.
Posterior Stabilized (PS) components are also for absent or non-functioning posterior cruciate ligament and severe anteroposterior instability of the knee joint.
The VEGA Knee System® and Columbus Total Knee System are designed for use with bone cement.

TECHNOLOGICAL CHARACTERISTICS

The addition of All Poly Tibia posterior stabilizing and cruciate retaining implants with an optional centralizer does not change the fundamental scientific technology of VEGA Knee System® or of Columbus Total Knee System.

Similar to the Triathlon® All-Polyethylene Posterior Stabilizing (PS) and Condylar Stabilizing (CS) tibial implants (K123166), the introduction of All Poly Tibia is a monoblock meniscal/tibial UHMWPE component whose design is based on the respective system's UHMWPE tibial insert and CoCrMo tibial components.
VEGA All Poly Tibia (PS) components are compatible with the articulating sizes of the VEGA femur and patella. Similarly, Columbus All Poly Tibia (CR deep dish) is compatible with the articulating sizes of the Columbus femur and patella. The optional centralizer was previously cleared in Aesculap's Excia Hip system (K042344). It is designed to ensure a consistent cement mantle around the keel.

PERFORMANCE DATA

As a result of the risk analysis, biomechanical testing and a comparison evaluation of wear was performed. The results of the wear evaluation, mechanical failure (break) and surface roughness analysis raised no new issues of safety and efficacy for the design modifications described herein. In addition to the data above, biocompatibility of the X-ray markers was provided as well as information on the validation and verification of the new instruments.